7-5/2021/EU/WC-0493

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(International Cell)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 03 APR 2024

To,

M/s. Metrochem API Private Limited,
Unit-IV, Plot No: 34B, 40B & 60B,
J.N. Pharma City, Thanam (V), Parawada (M),
Anakapalli District -531021, Andhra Pradesh, India

SUB:- Written Confirmation of **M/s. Metrochem API Private Limited, Unit-IV, Plot No: 34B, 40B & 60B, J.N. Pharma City, Thanam (V), Parawada (M), Anakapalli District -531021, Andhra Pradesh, India,** as per requirement of EU for import of active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India-Reg.

Sir,

Please refer to your online application no. WC/RE/2023/7788 dated 09.12.2023 submitted to CDSCO, Sub-Zone, Visakhapatnam and the recommendation received from ADC(I), Sub-Zone, Visakhapatnam on the above noted subject.

Written Confirmation as required for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC from India is herewith granted subject to the following conditions:-

1. The Active Pharmaceutical Ingredients shall confirm to Good Manufacturing Practices mentioned in the EU directives or other equivalent (GMP of WHO/ICH Q7).

2. The manufacturer is subject to regular, strict and transparent controls and to the effective enforcement of Good Manufacturing Practice, including repeated and unannounced inspections, so as to ensure a protection of public health equivalent to that in the EU.

3. The manufacturer is required to follow the Guidance document for Issue of Written Confirmation as issued by CDSCO.

4. Written Confirmation shall be produced by the Authorized Exporter as and when required by the Drug Regulatory Authority.

5. The Written Confirmation will be withdrawn in the events of non compliance of Standards.

6. This Written Confirmation, unless it is sooner suspended or cancelled, shall be valid for a period of three years.

7. In the event of any Non Compliance observed during inspections conducted by Local or International Drug Authorities, the same shall be forwarded to this office within 7 days of receipt of report.

8. In the event of any drug found not of standard quality, the same shall be reported to this office within 7 days of receipt of report.

9. The manufacturer is required to comply with the provisions of GSR 20(E), dated 18.01.2022.

Please note that Written Confirmation issued is liable to be suspended / cancelled, if any of the conditions stipulated above are not complied with or in case of violation of the provisions of the Drugs & Cosmetics Act, 1940 and the Rules thereunder as the case may be.

Please acknowledge the receipt.

Annexure No.	No. of Products	Date of Issue	Valid Upto
--	--	03 APR 2024	21.01.2027
01	27	03 APR 2024	21.01.2027
02	01	03 APR 2024	21.01.2027

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. : **WC-0493**

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s. Metrochem API Private Limited,**
Unit-IV, Plot No: 34B, 40B & 60B,
J.N. Pharma City, Thanam (V), Parawada (M),
Anakapalli District -531021, Andhra Pradesh, India

2. Manufacturer's licence number: **09/VSP/AP/2017/B/R**

Regarding the manufacturing plant under (1) of the following Active substance(s) exported to the EU for medicinal products for human use

List of API(s):

As per list enclosed as Annexures

The issuing Regulatory Authority hereby confirms that:

The standards of good manufacturing practice applicable to this manufacturing plant are at least equivalent to those laid down in the EU(= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of Inspection of the plant: 13.09.2023 to 15.09.2023

The Written Confirmation remains valid until: **21.01.2027**

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority: **Central Drugs Standard Control Organisation**
FDA Bhawan, Kotla Road,
New Delhi- 110 002, India

Name and function of responsible person: Dr. Rajeev Singh Raghuvanshi,
Drugs Controller General (India)

E-mail: dci@nic.in,
Telephone no.: +91-11-23236965
Fax no.: +91-11-23236973

03 APR 2024

Signature

Stamp of the authority and date

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

Annexure-01
WC-0493

CERTIFICATE NO. :

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: **M/s. Metrochem API Private Limited,**
Unit-IV, Plot No: 34B, 40B & 60B,
J.N. Pharma City, Thanam (V), Parawada (M),
Anakapalli District -531021, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Apixaban IHS	Manufacturing & Packing
02	Bempedoic Acid IHS	Manufacturing & Packing
03	Clopidogrel Bisulphate USP	Manufacturing & Packing
04	Clopidogrel Hydrogen Sulfate Ph.Eur	Manufacturing & Packing
05	Dapagliflozin Propanediol Monohydrate IHS	Manufacturing & Packing
06	Dexketoprofen Trometamol IHS	Manufacturing & Packing
07	Dexlansoprazole IHS	Manufacturing & Packing
08	Dimethindene Maleate Ph.Eur	Manufacturing & Packing
09	Empagliflozin IHS	Manufacturing & Packing
10	Esomeprazole Magnesium USP	Manufacturing & Packing
11	Esomeprazole Magnesium Trihydrate Ph.Eur	Manufacturing & Packing
12	Esomeprazole Sodium Ph.Eur	Manufacturing & Packing
13	Etoricoxib IHS	Manufacturing & Packing
14	Febuxostat IHS	Manufacturing & Packing
15	Itraconazole USP/Ph.Eur	Manufacturing & Packing
16	Lansoprazole USP/Ph.Eur	Manufacturing & Packing
17	Levocetirizine Dihydrochloride USP	Manufacturing & Packing
18	Lurasidone Hydrochloride IHS	Manufacturing & Packing
19	Omeprazole USP/Ph.Eur	Manufacturing & Packing
20	Omeprazole Magnesium USP/Ph.Eur	Manufacturing & Packing
21	Ozenoxacin IHS	Manufacturing & Packing
22	Pantoprazole Sodium Sesquihydrate Ph.Eur	Manufacturing & Packing
23	Posaconazole IHS	Manufacturing & Packing
24	Prucalopride Succinate IHS	Manufacturing & Packing
25	Rabeprazole Sodium USP/Ph.Eur	Manufacturing & Packing
26	Silodosin IHS	Manufacturing & Packing
27	Tofacitinib Citrate IHS	Manufacturing & Packing

ITEM(S) TWENTY-SEVEN (27) ONLY

The Written Confirmation remains valid until: 21.01.2027

Signature

10 3 APR 2024

Stamp of the authority and date

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
Central Drugs Standard Control Organization

CERTIFICATE NO. :

Annexure-02
WC-0493

Written confirmation for active substances imported into the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

1. Name and address of site: M/s. Metrochem API Private Limited,
Unit-IV, Plot No: 34B, 40B & 60B,
J.N. Pharma City, Thanam (V), Parawada (M),
Anakapalli District -531021, Andhra Pradesh, India

List of APIs:

S. No.	Active substance(s)	Activity(ies)
01	Oxiconazole Nitrate IHS	Manufacturing & Packing

ITEM(S) ONE (01) ONLY

This certificate is being issued subject to condition that the firm shall obtain NOC from the Competent Authority, on case to case basis, to manufacture the above mentioned active substances for the purpose of export only, as the above mentioned active substances are not approved for manufacture for sale in India.

The Written Confirmation remains valid until: 21.01.2027

Signature

Stamp of the authority and date

03 APR 2024